

Package leaflet: Information for the user
Tylex® 30 mg / 500 mg hard capsules

**Codeine phosphate hemihydrate,
paracetamol**

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Tylex is and what it is used for
2. What you need to know before you take Tylex
3. How to take Tylex
4. Possible side effects
5. How to store Tylex
6. Contents of the pack and other information.

1. What Tylex is and what it is used for

Tylex contains two different medicines called paracetamol and codeine phosphate hemihydrate. Codeine belongs to a group of medicines called opioid analgesics which act to relieve pain. It can be used on its own or in combination with other pain killers. Paracetamol is an analgesic which acts to relieve pain and fever.

Tylex is used in adults and adolescents from 12 to 18 years of age for the short-term relief of moderate pain that is not relieved by other painkillers such as paracetamol or ibuprofen alone.

2. What you need to know before you take Tylex

Do not take Tylex:

- if you are allergic to paracetamol or codeine phosphate hemihydrate, or any of the other ingredients of this medicine (listed in section 6).
- if you are a child under 12 years old.
- for pain relief in children and adolescents (0-18 years of age) after removal of their tonsils or adenoids due to obstructive sleep apnoea syndrome.
- if you know that you metabolise very rapidly codeine into morphine.
- if you have severe asthma attacks or severe breathing problems.
- if you are an alcoholic.
- if you have recently had an operation on your liver, gallbladder or bile duct (biliary tract).
- if you have recently had a head injury.
- if you have been told by your doctor that you have increased pressure in your head. Signs of this include: headaches, being sick (vomiting) and blurred eyesight.
- if you are breastfeeding.

- if you are taking medicine to treat depression called MAOIs (monoamine oxidase inhibitors) or have taken them in the last 2 weeks. MAOIs are medicines such as moclobemide, phenelzine or tranylcypromine (see ‘Taking other medicines’).

Warnings and precautions

Codeine is transformed to morphine in the liver by an enzyme. Morphine is the substance that produces pain relief. Some people have a variation of this enzyme and this can affect people in different ways. In some people, morphine is not produced or produced in very small quantities, and it will not provide enough pain relief. Other people are more likely to get serious side effects because a very high amount of morphine is produced. If you notice any of the following side effects, you must stop taking this medicine and seek immediate medical advice: slow or shallow breathing, confusion, sleepiness, small pupils, feeling or being sick, constipation, lack of appetite.

Rarely, increasing the dose of this medicine can make you more sensitive to pain. If this happens, you need to speak to your prescriber about your treatment.

Children and adolescents

Tylenol should be used with extreme caution in adolescents between 12 and 18 years. An alternative medicine should be considered if at all possible.

Use in children and adolescents after surgery

Codeine should not be used for pain relief in children and adolescents (0-18 years of age) after removal of their tonsils or adenoids due to Obstructive Sleep Apnoea Syndrome.

Use in adolescents between 12 and 18 years with breathing problems

Codeine is not recommended in adolescents between 12 and 18 years with breathing problems, since the symptoms of morphine toxicity may be worse in these children.

Talk to your doctor or pharmacist before taking Tylenol:

- if you have liver or kidney disease
- if you have an under-active thyroid gland
- if you suffer from urinary problems (e.g. difficulty in passing water) including those associated with an enlarged prostate gland
- if you have a disease of the Adrenal gland called Addison’s disease
- if you have a condition which weakens the muscles called myasthenia gravis
- if you have a condition called ulcerative colitis which affects your colon
- if you have a condition that causes your body to have less blood than it should
- if you have fits (seizures)
- if you are suffering from shock
- if you are elderly
- if you feel weak.
- If you have severe illnesses, including severe renal impairment or sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), or you suffer from malnutrition, chronic alcoholism or if you are also taking flucloxacillin (an antibiotic). A serious condition called metabolic acidosis (a blood and fluid abnormality) has been reported in patients in these situations when paracetamol is used at regular doses for a prolonged period or when paracetamol is taken together with flucloxacillin. Symptoms of metabolic acidosis may include: serious breathing difficulties with deep rapid breathing, drowsiness, feeling sick (nausea) and being sick (vomiting).

Other medicines and Tylenol

Do not take Tylenol with any other paracetamol-containing products. Many other medicines contain paracetamol, including some you can buy without a prescription (for example some cold and “flu” remedies).

Do not take this medicine, and tell your doctor or pharmacist, if you are taking

- Medicines to treat depression called MAOIs (monoamine oxidase inhibitors) or have taken them in the last 2 weeks.
MAOIs are medicines such as moclobemide, phenelzine, tranylcypromine

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines:

- Chloramphenicol - an antibiotic used for infections
- The oral contraceptive pill
- Medicines to treat anxiety or depression (e.g. fluoxetine, paroxetine or sertraline)
- Other painkillers (including opioids)
- Medicines to help you sleep
- Warfarin (a medicine used to thin the blood)
- Medicines used to treat stomach problems, sickness or feeling sick (including metaclopramide and domperidone)
- Cholestyramine (a medicine used to lower cholesterol levels in the blood)
- Flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called high anion gap metabolic acidosis) that must have urgent treatment (see section 2).
- Rifampicin - an antibiotic used for infections
- Phenytoin, phenobarbital, carbamazepine (medicines to treat epilepsy)
- Quinidine (a medicine used to treat heart rhythm disorders)
- Medicines to help relax muscles
- Neuroleptics (a medicine use to treat schizophrenia and bipolar disorder)
- Bupropion (a medicine use to treat depression and smoking cessation)
- Any other medicine, including medicines obtained without a prescription (e.g. St. John's wort).

Concomitant use of Tylex and sedative medicines such as benzodiazepines or related drugs increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible. However if your doctor does prescribe Tylex together with sedative medicines the dose and duration of concomitant treatment should be limited by your doctor.

Please tell your doctor about all sedative medicines you are taking, and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

Tylex with food, drink and alcohol

Do not drink alcohol whilst taking Tylex. If you regularly drink large amounts of alcohol, you are at risk of damaging your liver when taking paracetamol.

Pregnancy, breast-feeding and fertility

Do not take Tylex if you are pregnant or trying to get pregnant.

The use of Tylex should be avoided during labour.

Do not take Tylex while you are breastfeeding. Codeine and morphine passes into breast milk.

Driving and using machines

Tylex may make you feel dizzy or tired. If this happens to you, do not drive a vehicle, operate machinery or carry out complex tasks.

Tylex contains sodium metabisulfite and sodium benzoate

Tylex contains **sodium metabisulfite** and is unsuitable for people who are sensitive to sulfite. People with **asthma** are more likely to be sensitive to sulfite. Therefore, you should talk to your doctor before taking Tylex if you are sensitive to sulfite or if you suffer from **asthma**. May rarely cause severe hypersensitivity reactions and bronchospasm.

This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially ‘sodium free’.

This medicine contains 0.3 mg benzoate salt in each capsule, which is equivalent to 0.3 mg / 547.86 mg capsule.

3. How to take Tylex

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults and the elderly

- The recommended dose is one or two capsules every 6 hours
- Do not take more than eight capsules in 24 hours
- Swallow the capsule with water
- The label will tell you how many capsules to take and how often
- If you are elderly you may need to take fewer capsules. Please speak to your doctor about this.

Use in children and adolescents

Children aged less than 12 years:

Tylex should **not** be taken by children below the age of 12 years, due to the risk of severe breathing problems.

Children aged 12 to 15 years:

One capsule every 6 hours when necessary (do not take more than four capsules in 24 hours).

Children aged 16 to 18 years:

One to two capsules every 6 hours when necessary (do not take more than eight capsules in 24 hours).

Duration of treatment

This medicine should not be taken for more than 3 days. If the pain does not improve after 3 days, talk to your doctor for advice.

If you feel the effect of this medicine is too strong or too weak, talk to your doctor or pharmacist.

If you take more Tylex than you should

Do not take more Tylex than you should. If you accidentally take too much, immediately go to the nearest hospital casualty department or your doctor.

You should go to hospital, even if you feel well, because there is a risk of delayed, serious liver damage.

If you forget to take Tylex

It is important that you take your capsules at the right times. If you forget to take a dose, take it as soon as you remember, then carry on as before.

Do not take more than two capsules at once and do not take more than eight capsules in each 24-hour period.

If you stop taking Tylex

You may feel irritable or restless when treatment with Tylex is stopped.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Seek immediate medical help if you have any of the following symptoms:

- **Feeling faint**
- **Swelling of the hands, feet, ankles, face, lips or throat or blistering of the skin, mouth, eyes and genitals. You could also notice an itchy, lumpy rash (hives) or nettle rash. This may mean you are having an allergic reaction to this medicine**
- **Difficulty in breathing or wheezing, shortness of breath**
- **You get serious skin reactions. Very rare cases have been reported**

Frequency “Not known” (frequency cannot be estimated from the available data): A serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2).

Tell your doctor or pharmacist if you notice any of the following side effects get serious or last longer than a few days:

- Allergic reactions, including skin rash
- Feeling sick or being sick
- Light-headedness
- Confusion
- Dizziness
- Feeling sleepy
- Headache
- Mood changes
- Hallucination
- Difficulty in breathing, shortness of breath, wheezing, tightness in the chest (bronchospasm)
- Constipation
- Severe stomach pains (pancreatitis)
- Stomach pains
- Itchy skin
- Deafness
- Difficulty in passing water (urine)
- Becoming dependent on codeine
- Problems with the blood (thrombocytopenia, agranulocytosis, neutropenia, leucopenia). This is usually shown by tiredness, weakness, or unexplained bruising or bleeding. This side effect is very rare.

Taking codeine regularly for a long time can lead to addiction. This might cause you to feel restless and irritable when you stop taking Tylex.

Taking a lot of Tylex for a long time can cause deafness.

Reporting of side effects

If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance; Website: www.hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Tylex

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after EXP.

The expiry date refers to the last day of that month. Do not store above 25°C. Store in the original package in order to protect from light and moisture.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Further information

What Tylex contains

- The active substances are codeine phosphate hemihydrate and paracetamol. Each capsule contains 30mg codeine phosphate hemihydrate and 500mg paracetamol.
- The other ingredients are sodium metabisulfite (E223), pregelatinised potato starch, calcium stearate, docusate sodium with sodium benzoate (E211). The capsule is made of gelatin, titanium dioxide (E171), erythrosine (E127) and indigo carmine (E132). The printing ink contains shellac, propylene glycol, ammonium hydroxide and iron oxide black (E172).

What Tylex looks like and contents of the pack

Tylex capsules are hard gelatin capsule with white opaque body and red cap, both with “C30” printed in black.. They are supplied in blister strips containing 8, 24 or 100 capsules. Not all pack sizes may be marketed.

Marketing Authorisation Holder

UCB (Pharma) Ireland Ltd, United Drug House, Magna Drive, Magna Business Park, Citywest Road, Dublin 24, Ireland.

Manufacturer

Lusomedicamenta Sociedade Técnica Farmacêutica, S.A, Estrada Consiglieri Pedroso, 66, 69-B, Queluz de Baixo, 2730-055 Barcarena, Portugal.

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If this leaflet is difficult to read and you would like it in a different format, please contact UCB (Pharma) Ireland Ltd, United Drug House, Magna Drive, Magna Business Park, Citywest Road, Dublin 24, Ireland.